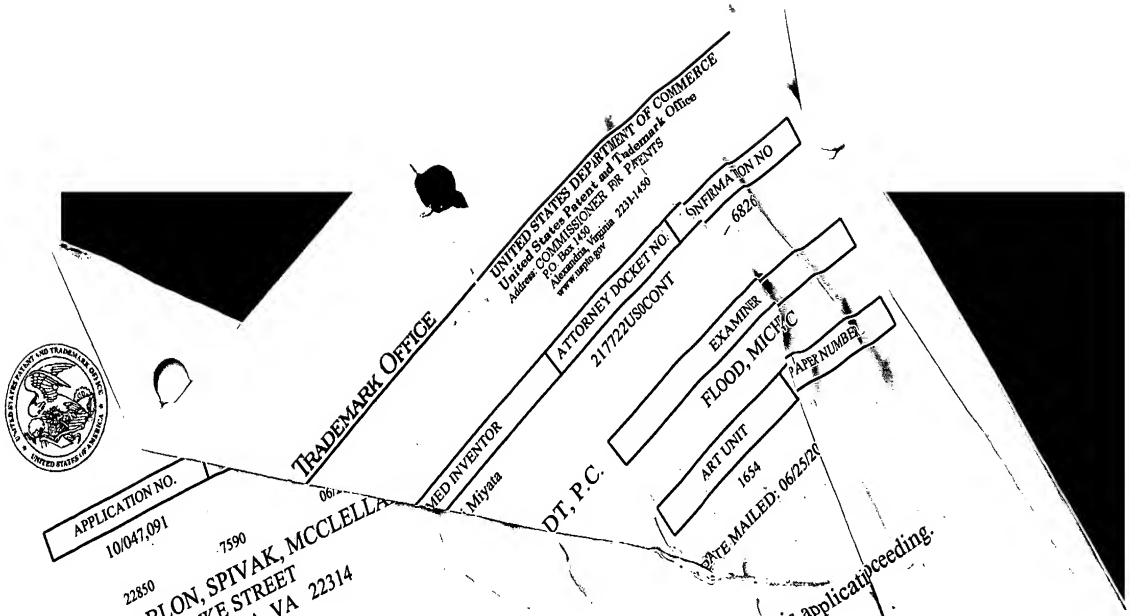


Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 10/047,091 | Miyata et al. |
| Examiner | Art Unit |
| Michele Flood | 1654 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *Jan 17, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13* is/are rejected.

7)☒ Claim(s) *14-16* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *Jan 17, 2002* is/are a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some* c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4*

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

## DETAILED ACTION

Acknowledgment is made of the receipt and entry of the preliminary amendment filed on January 17, 2002. Acknowledgment is made of Applicant's cancellation of Claims 1-12, and newly added Claims 13-16.

### *Priority*

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

### *Specification/Abstract*

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, it is strongly suggested that the phrase "The hyaluronic gel according to Claim 1" should be deleted from the language of the abstract, as there is no Claim 1 in the present application. For more clarity, Applicant should delete the phrase and add which to overcome the rejection.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Paparella et al. (U) and Leschiner et al. (A).

Applicant claims a method of producing hyaluronic acid gel which comprisises adusting a hyaluronic acid solution to a pH 3.5 or below, and freezing and thawing the solution at least once.

Paparella teaches a method of functionalizing hyaluronic acid or a benzyl ester of hyaluronic acid with glycidyl acrylate to introduce double bonds, followed by crosslinking by gamma-irradiation. Then, the gels were air-dried and oven dried. Portions of the functionalized solutions of hyaluronic acid were acidified to pH 3 with citric acid. Hyaluronic acid gels (MW 200,000) readily formed at lower concentrations if pH was reduced to 3, prior to gamma-irradiation. A solution of benzyl ester of hyaluronic acid of 50% esterification, HYAFF11-p50, at pH 3 formed microgels which were dispersed in solution.

Leshchiner teaches viscoelastic gel slurries formed from a polymeric gel, consisting of hyaluronan or a derivative thereof (hyaluronic acid and its biological salts. The biocompatible viscoelastic gel slurries consist of two phases; the first being a polymeric gel swollen in an aqueous medium, and the second being a fluid phase in which the gel has is an elastoviscous aqueous solution of a polymer. See Column 2, lines 7-36 and Column 3, lines 3-5. Leshchiner teaches methods of making fibrous or tubular hyaluronic acid gel by crosslinking hylan to form a swollen or massive product. See Columns 12-15, "EXAMPLES 4-8". In "EXAMPLE 3", Leshchiner teaches a method of making a hyaluronic acid gel comprising the acidification and freeze-drying of aqueous hyaluronic acid solution. In Column 24, lines 16-35, a method of using the viscoelastic hylan gel mixed slurry as a biomedical material is taught.

Therefore, each of the references of Paparella and Leshchiner is deemed to anticipate the claimed subject matter.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Pouyani et al. (B).

Applicant's claimed invention was set forth above.

Pouyani teaches a method of crosslinking hyaluronate with dihydrazide, then adding carbodiimide so that the hyaluronate and dihydrazide react to form a crosslinked hyaluronic acid gel so that the resulting gel strength is easily manipulated. The crosslinked hyaluronic acids taught by Pouyani form biocompatible gels or hydrogels that are viscous or semi-solid and jelly like and are useful for biological, medical, surgical and cosmetic applications. See Column 2, lines 1-47. A method of making the hyaluronic acid gels are taught in Column 7, lines 27-37 bridging Column 8, lines 1-20, which comprises acidifying aqueous hyaluronate to a pH of about 2 to 8, preferably 3 to 6, and freezing and thawing the solution at least once. In Column 13, lines 56-67, Pouyani teaches crosslinked hydrogels that are pore-containing matrices wherein therapeutically active agents can be incorporated which can be subject to sustained release and physical degradation over a period of time. A hyaluronic acid gel in the form of a polymer film or sheet can be spread onto a backing or substrate. See Column 15, lines 49-61. A method of making a fibrous hyaluronic acid gel is taught in Column 17, lines 29-52.

The reference anticipates the claimed subject matter.

***Allowable Subject Matter***

3. Claims 14-16 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF

June 19, 2003